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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Kohji Kawahara

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08/17/2009

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EXAMINER

HUANG, GIGI GEORGIANA

ART UNIT

PAPER NUMBER

1612

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/540,835	Applicant(s) KAWAHARA ET AL.	
	Examiner GIGI HUANG	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6,8-15,21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-6,8-15,21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. The response filed April 27, 2009 has been received, entered and carefully considered. The response affects the instant application accordingly:
 - a. Claims 2-6, 8-15 have been amended.
 - b. Claim 1, 7, 16-20 has been cancelled.
 - c. Claim 21-22 has been added.
2. Claims 2-6, 8-15, 21-22 are pending in the case.
3. As claims 2-6 and 8-15 have been amended to direct to the method of newly added claim 21, and claims 16-20 are cancelled, there no longer exists composition claims and the claims 2-6 and 8-15 are rejoined to method under examination.
4. Claims 2-6, 8-15, 21-22 are present for examination.
5. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.
6. All grounds not addressed in the action are withdrawn or moot.
7. New grounds of rejection are set forth in the current office action.

New Grounds of Rejection

Due to the amendment of the claims the new grounds of rejection are applied:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is unclear as it recites drugs and classes of drugs that are not consistent for the conditions recited in the independent claim. The drugs are broader than what would be considered for the conditions in the independent claim cited with closed language (e.g. remedy for glaucoma, sulfa agent, miotic, vitamin B12, beta blocker). It is unclear how they would be used for the conditions listed. The resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

a. (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 2-5, 8-15, 21-22 is rejected under 35 U.S.C. 102(b) as being anticipated by Tojo et al. (WO 01/26648).

It is noted that U.S. Pat. 7052714 will be used as the translation for WO 01/26648 and all references are to the U.S. Patent.

Tojo et al. teaches transdermal preparations comprising an adhesive with a drug (plaster) with a release membrane, and a lining film (support). Drugs taught include anti-virals (e.g. acyclovir, ganciclovir) which is useful for cytomegalovirus retinitis (ocular infection) and corticosteroids (e.g. prednisolone) a anti-inflammatory/antiallergic known in the art to be useful for many conditions including uveitis and conjunctivitis. The patch

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comprises percutaneous absorption enhancer including polyoxyethylene oleyl ether, fatty acids, fatty acid esters, and higher alcohols at 5-30w/w.%; adhesives including acrylics (e.g. Nippon Carbide Industries PE-300, an alkyl (meth)acrylate-vinyl acetate copolymer), silicone base, or rubber base (e.g. styrene-isoprene-styrene copolymer) at 1-20wt.% and tackifier (e.g. thickeners, coagulation enhancers, paraffin); and the drug at 1-20wt.% which can be adjusted as desired based on the disease to be treated and its severity.

The patch can be applied to any desired body surface including the eyelid (see full document, specifically, Abstract, Col. 2 line 10-68, Col. 5 line 27-col. 7 line 40, col. 13 line 55- Col. 15 line 20, claim 7-10, 13-14, 16). Examples are presented where the general teaching for the patches has the components such as the acrylic, the enhancer, and the drug meet the claims. Example 2, 3, and 5 have the acrylic at 5.0 g (100parts, thereby 1 part is 0.05g), the enhancer is at 0.6g (12 parts), the drug is at 0.3g (6 parts-Ex.2), 0.45g (9 parts-Ex.3), and 0.3g (6 parts-Ex.5). General teaching in Example 11 for the styrene-isoprene-styrene patches have the styrene- isoprene-styrene at 0.9g (100parts, thereby 1 part is 0.009g),the isopropyl myristate enhancer is at 0.3g (33.3 parts),and the drug is at 0.15g (16.6 parts), the paraffin (tackifier) is at 0.15g (16.6 parts) meeting the claims.

It is noted that the claim reciting a method for transferring a remedy(drug) for ophthalmic diseases to an ophthalmic topical tissue comprising applying a transdermal drug delivery system comprising a plaster and a support, to the skin surface of an eyelid. However, transfer of the drug inherently occurs when a composition with the

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recited components (such as transdermal formulation) is applied to the cited mode of administration (applied to the skin of an eyelid). In fact, drug transfer is inherent to transdermal formulations by the nature of the art. Additionally, the amount of transfer and penetration would be inherent to the components of the composition and when delivered in the same manner as claimed, the effects of the composition would be the same such as penetration are a result of the components of the composition and the mode of administration which are met by the art and the resulting properties and effects would inherently be met. It is also noted that the application of the patch as taught in Tojo would inherently treats anyone who may have the conditions recited.

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 2-6, 8-15, 21-22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Higo et al. (U.S. Pat. 5866157) in view of Trimming et al. (U.S. Pat. Pub. 2001/0006968) in view of Tojo et al. (WO 01/26648) in view of Lerner et al. (WO 97/18855).

It is noted that U.S. Pat. 7052714 will be used as the translation for WO 01/26648 and all references are to the U.S. Patent.

Higo et al. teaches the use of a transdermal patch which has increased percutaneous absorbability of the drug and reduced irritation to the skin for the administration of active agents including ketotifen taught as a known antiallergic, with a reservoir and a support. Higo also teaches the patch to have an absorption enhancer, a hydrophobic high molecular material (adhesive), a tackifying resin, other components. The amount of active (e.g. ketotifen) is 0.1 to 20%, hydrophobic high molecular material is 15 to 65%, the tackifier is 10 to 70%, and the absorption enhancer is from 0.01 to 20%. The hydrophobic high molecular material can comprise styrene-isoprene-styrene block copolymers, isoprene rubber, and acrylic polymers such as copolymer of methacrylate, acrylic acid, and vinyl acetate. The absorption enhancer can comprise C6-C20 fatty acids, fatty alcohols, fatty acid esters or ethers, and other materials (see full document). There are examples of ketotifen matrix patches on a support (backing) wherein the amount of the components meet the claims such as Example 1: styrene-isoprene-styrene at 16.5% for Example 1 (100 parts/16.5g, 1 part=0.165g), tackifier-Alicyclic saturated hydrocarbon resin at 29.5% (178.8 parts), and ketotifen fumarate at 2% (12.1 parts); and Example 7: styrene-isoprene-styrene at 36.5% for Example 1 (100 parts/36.5g, 1 part=0.365g), tackifier-Alicyclic saturated hydrocarbon resin at 10% (27.4 parts), and ketotifen fumarate at 3.5% (9.59 parts)

Higo does not expressly teach an example with an acrylic polymer in the amounts claimed. Higo does teach that the hydrophobic high molecular material can comprise styrene-isoprene-styrene block copolymers, isoprene rubber, and acrylic polymers such as copolymer of methacrylate, acrylic acid, and vinyl acetate whereby

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these materials are taught to be functional equivalents. Higo also teaches that ketotifen is a known antiallergic with examples.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute the acrylic polymer for the styrene-isoprene-styrene block copolymers in the ketotifen examples presented as Higo teaches that these hydrophobic high molecular materials are functional equivalents. It is desirable for manufacturers to have analogous choices to substitute the hydrophobic high molecular material when motivated by pricing, availability, or desired properties of the polymer such as the degree of adhesiveness, for the production of the final product.

Higo does not expressly teach placement on the eyelid. Higo does teach that ketotifen is a known antiallergic.

Timming et al. teaches that ketotifen (e.g. ketotifen fumarate) is useful for the treatment of allergic conjunctivitis, such as seasonal allergic conjunctivitis (see full document).

Tojo teaches that transdermal patches for ophthalmic conditions are known and can be applied to any body surface including the eyelid (Col. 7 line 35-40).

Lerner teaches that the skin of the eyelid has a resistance lower than that on the rest of the skin surface (Page 37 line 38- Page 38 line 1).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the ketotifen patch on the eyelid for its known use, as suggested by Timming, Tojo, and Lerner, and produce the instant invention. It would

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have been obvious to one of skill in the art as ketotifen is known in the art to be used for allergic conditions including allergic conjunctivitis and transdermal patches are known to provide safe continuous delivery as addressed by Higo, it would be obvious to use the transdermal patch for allergic conjunctivitis and place the patch as close to the eye as ocular transdermal patches are known as addressed by Tojo, and as it is taught by Lerner that the skin surface over the eyelid has less resistance than the rest of the skin of the body to provide not only direct delivery but more effective delivery as there is better penetration from the lower resistance also providing motivation (improved delivery-lower resistance) for one of skill in the art to do so.

One of ordinary skill in the art would have been motivated to do this because it is desirable to provide better delivery of a known composition for a known treatment with a known method of administration with greater efficacy due to the lowered resistance of the eyelid.

It is noted that the transfer of a remedy (drug) intrinsically occurs when a composition with the recited components (such as transdermal formulation) is applied to the cited mode of administration (applied to the skin of an eyelid). In fact, drug transfer is intrinsic to transdermal formulations by the nature of the art.

Double Patenting

11. Claim 2-5, 8-15, 21-22 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-7, 11, 48 of copending Application No. 10/569772 in view of Tojo et al. (WO 01/26648).

The claims of the conflicting application are drawn to the application of a muscarinic receptor agonist in a base matrix (acrylic, silicone, rubber adhesive) to the skin surface of the eyelid to promote lacrimal fluid secretion which is known to be useful for keratoconjunctivitis, a form of allergic conjunctivitis (see Wong et al.-Abstract) and would intrinsically treat the condition.

The conflicting claims do not recite a support. However, as taught by Tojo et al. it is obvious to add a support (lining film) to the base matrix as part of a transdermal delivery system to improve adhesion. As a result, the instant claim is obvious over the copending claims and encompasses the specific conflicting claims.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

12. Applicant's arguments in regards to Tojo et al. filed 4/17/2009 have been fully considered but they are not persuasive. Applicant asserts that the amended claims are to the conjunctiva, lacrimal tissue and cornea and is different than that of Tojo. This is not persuasive as the claims are to a method for transferring a remedy for certain ophthalmic conditions to external ophthalmic tissue wherein application of a transdermal form with a plaster layer on a support with the recited composition materials applied to the same site (eyelid) inherently transfers the drug through the skin and passes through of the external portion of the eye to the internal portion of the eye.

A drug transfer is inherent to transdermal formulations by the nature of the art. Additionally, the amount of transfer and penetration would be inherent when the components of the composition are delivered in the same manner as claimed, as the

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effects of the composition are the same when the components of the composition and the mode of administration are the determining factors for the results. When they are met, the effects are the same. It is also noted that the application of the patch as taught in Tojo would inherently treats anyone who may have the conditions recited.

Accordingly, this is reflected in the rejection of the claims above.

Conclusion

13. Claims 2-6, 8-15, 21-22 are rejected.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-

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9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612